Commonly Asked Questions About the US ART Clinic Reporting System

Background Information, Data Collection Methods, Content and Design of the Report, and Additional Information About ART in the United States

1. How many people in the United States have infertility problems?

The latest data on infertility available to the Centers for Disease Control and Prevention (CDC) are from the 2011–2013 National Survey of Family Growth. (For more details about the data, see http://www.cdc.gov/nchs/nsfg/key_statistics/i.htm#infertility.)

- Of the approximately 61 million women aged 15–44 years in 2011–2013, about 6.9 million, or 11%, had received infertility services at some time in their lives. (Infertility services include medical tests to diagnose infertility, medical advice and treatments to help a woman become pregnant, and services other than routine prenatal care to prevent miscarriage.)
- Additionally, about 6% of married women aged 15–44 years are infertile (unable to get pregnant after at least 12 consecutive months of trying to conceive).

2. What is assisted reproductive technology (ART)?

Although various definitions have been used for ART, the definition used in this report is based on the 1992 law that requires CDC to publish this report. According to this definition, ART includes all fertility treatments in which either eggs or embryos are handled. In general, ART procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman. They do NOT include treatments in which only sperm are handled (i.e., intrauterine insemination) or procedures in which a woman takes drugs only to stimulate egg production without the intention of having eggs surgically retrieved.

The main type of ART is **in vitro fertilization (IVF).** IVF involves extracting a woman's eggs, fertilizing the eggs in the laboratory, and then transferring the resulting embryos into the woman's uterus through the cervix. For some IVF procedures, fertilization involves a specialized technique known as intracytoplasmic sperm injection (ICSI). In ICSI, a single sperm is injected directly into the woman's egg.

Other types of ART exist, but are rarely performed. **Gamete intrafallopian transfer (GIFT)** involves using a fiber optic instrument called a laparoscope to guide the transfer of unfertilized eggs and sperm (gametes) into the woman's fallopian tubes through small incisions in her abdomen. **Zygote intrafallopian transfer (ZIFT)** involves fertilizing a woman's eggs in the laboratory and then using a laparoscope to guide the transfer of the fertilized eggs (zygotes) into her fallopian tubes.

In addition, ART often is categorized according to whether the procedure was started with the intent to freeze all eggs or embryos (banking), whether the procedure used a woman's own eggs (nondonor) or eggs from another woman (donor), whether the eggs were frozen and thawed before use, and whether the embryos used were newly fertilized (fresh) or previously fertilized, frozen, and then thawed (frozen).

3. What is an ART cycle?

Because ART consists of several steps over an interval of approximately 2 weeks, an ART procedure is typically referred to as a **cycle** of treatment rather than a procedure at a single point in time. The start of an ART cycle is when a woman begins taking drugs to stimulate egg production or starts ovarian monitoring with the intent of having embryos transferred. For the purposes of this report, data on all cycles that were started, even those that were discontinued before all steps were undertaken, are counted in the clinic's success rates.

4. How do US ART clinics report data to CDC about their success rates?

CDC contracts with a statistical survey research organization, Westat, to obtain the data published in the *Fertility Clinic Success Rates Report*. Westat maintains a list of all ART clinics known to be in operation, identifies new clinics throughout the year, and tracks clinic reorganizations and closings. This list includes clinics and individual providers that are members of the Society for Assisted Reproductive Technology (SART) as well as clinics and providers that are not SART members. Westat maintains the National ART Surveillance System (NASS), the web-based data collection system that all ART clinics use to submit data to CDC. Clinics either electronically enter or import data into NASS for each ART cycle started in a given reporting year. SART-member clinics can report directly to SART, and SART submits the data to NASS. The data collected include de-identified information on the patient's medical history (such as infertility diagnoses), clinical information pertaining to the ART procedure, and information on resulting pregnancies and births.

5. Why is the report of 2013 success rates being published in 2015?

Before success rates based on live births can be calculated, every ART pregnancy must be followed up to determine whether a birth occurred. Therefore, the earliest possible date that clinics can report complete annual data is about 9 months past the end of the reporting year, when all the births have occurred. Accordingly, the results of all the cycles initiated in 2013 were not known until October 2014. After ART outcomes are known, the following occurs before the report is published:

- Clinics enter their 2013 data into NASS and verify the data's accuracy before submitting the data at the end of 2014 to Westat.
- Preliminary data for individual fertility clinic tables are prepared and made available in the spring of 2015 on CDC's website at http://www.cdc.gov/art/reports/.
- After CDC conducts comprehensive data checks, the full report with all fertility clinic tables and the National Summary table is prepared and published in the summer of 2015 on the CDC website at http://www.cdc.gov/art/reports/.

These steps are essential for ensuring that the report provides the public with correct information regarding each clinic's success rates.

6. Which clinics are represented in this report?

The data in this report come from 467 fertility clinics that provided and verified information about the outcomes of the ART cycles started in their clinics in 2013.

Although almost all clinics that provided ART services in the United States during 2013 are represented in this report, data from 30 clinics or practitioners are not included because they did not report as required. Clinics and

practitioners known to have been in operation as of January 1, 2013, that did not report and verify their data are listed in this report as nonreporters, as required by law (see Appendix C: 2013 Nonreporting Clinics, by State on pages 573–574). Given the estimated number of ART cycles performed in nonreporting clinics, we estimate that ART surveillance covered 98% of ART cycles performed in the United States in 2013. We will continue to make every effort to include in future reports all clinics and practitioners providing ART services.

7. Why aren't the clinics ranked by their success rates?

Many factors contribute to the success rate of an ART procedure, and a difference in success rates between two ART clinics may reflect differences in the groups of patients treated, the types of procedures performed, or other factors. More explanations on how to use the success rates and other statistics published in this report are in the Introduction to Fertility Clinic Tables section (see pages 11–20). The report should be used to help people considering an ART procedure find clinics where they can meet personally with ART providers to discuss their specific medical situation and their likelihood of success using ART. Contacting a clinic also may provide additional information that could be helpful in deciding whether or not to use ART. Because ART offers several treatment options for infertility, there are many other factors that may affect the decision. This report may be a helpful starting point for consumers to obtain information and consider their options.

8. Does this report include all ART cycles performed by the reporting clinics?

This report includes 190,773 ART cycles performed in 2013 by the 467 clinics that reported their data as required. Of those 190,773 cycles, 27,564 were cycles started with the intent of cryopreserving (freezing) and storing all resulting eggs or embryos for potential future use. Because these cycles cannot result in pregnancies or births, they are not included in the majority of clinic success rates. Instead, the number of banking cycles are included in the total number of cycles performed, and the number of banking cycles by age group are reported.

Of the 190,773 total cycles, 2,655 were cycles started with the intention of thawing a frozen egg for fertilization and transfer. These cycles are not included in any clinic success rates. Instead, the number of cycles using frozen eggs is shown for each clinic in their table as part of the total number of cycles performed. The 190,773 total cycles performed in 2013 excludes 67 cycles started in which a new treatment procedure was being evaluated. The number of new treatment procedures performed is shown for each clinic in footnote "d" of their table.

9. How are the success rates determined?

This report presents several measures of success for ART, including the percentage of ART cycles that result in a pregnancy. (Please note that not all pregnancies result in live birth; some pregnancies may result in miscarriage, induced abortion, or stillbirth.) All live-birth deliveries were reported to the ART clinic by either the patient or the patient's obstetric provider. Because this report is geared toward patients, the focus is on the percentage of cycles resulting in live births. Singleton live births, births of a single, live infant, are emphasized as a separate measure of success because they have a much lower risk than multiple-infant births for adverse infant health outcomes, including prematurity, low birth weight, disability, and death. Success rates were calculated at various steps of the ART cycle to provide a complete picture of the chances for success as the cycle progresses.

10. What are my chances of getting pregnant using ART?

Many consumers ask this question because they assume that the pregnancy will lead to a live birth. Unfortunately, not all ART procedures that result in a pregnancy lead to the delivery of a live infant. For example, 93,787 fresh nondonor ART cycles were started in 2013. Of those, 33,425 (36%) led to a pregnancy, but only 27,406 (29%) resulted in a live birth. In other words, 6,019 (almost 1 in 5) of ART pregnancies did not result in a live birth. The percentage of cycles resulting in live births will give a more accurate answer to the question, "If I have an ART procedure, what is my chance that I will have a baby?"

It is important to note that ART success rates vary in the context of patient and treatment characteristics. These characteristics include age, infertility diagnosis, number of embryos transferred, type of ART procedure, use of techniques such as ICSI, and history of previous births, miscarriages, and ART cycles.

11. If a patient has had more than one ART treatment cycle, how is the success rate calculated? Alternatively, how many cycles does a patient usually go through before getting pregnant?

As required by law, this report presents ART success rates in terms of how many cycles were started each year. Because clinics report information based on outcomes for each cycle started, success rates on a "per patient" basis, or the number of cycles that an average patient may undergo before achieving success, are not presented in this report. While it is possible to achieve success with one ART cycle, success rates vary in the context of patient and treatment characteristics. Consumers should consult with their physician to understand their specific medical situation and their chances of pregnancy using ART.

12. What quality control steps are used to ensure data accuracy?

To have their success rates published in this annual report, clinics have to submit their data in time for analysis and the clinics' medical directors have to verify by signature that the tabulated success rates are accurate. Then, Westat conducts an in-house review and contacts the clinics if corrections are necessary. After the data have been verified, a quality control process called validation begins.

This year, 35 (about 7%) of the 467 reporting clinics were selected after taking into consideration some cycle and clinic characteristics and whether the clinic had been selected before. (See Appendix A: Technical Notes on page 523 for a more detailed presentation of sampling strategy.) Members of the Westat Validation Team visit these clinics and review medical record data for a sample of the clinic's ART cycles. For each cycle, the validation team abstracts information from the patient's medical record. The abstracted information is then reviewed onsite and compared with the data submitted for the report.

The data validation process does not include any assessment of clinical practice or overall record keeping. Validation primarily helps ensure that clinics submit accurate data. It also serves to identify any systematic problems that could cause data collection to be inconsistent or incomplete. Findings and discrepancy rates from the 2013 validation visits will be available on the CDC website later this year at http://www.cdc.gov/art/reports/.

13. How does CDC use the data collected but not reported in the annual *Assisted Reproductive Technology Fertility Clinic Success Rates Report* and *National Summary Report?*

CDC uses the data collected and not reported in the annual ART reports for surveillance of emerging practice patterns, surveillance of success rates by patient and practice characteristics, evaluation of emerging ART research questions, and the monitoring of safety and efficacy issues related to ART treatment for improving maternal and child health outcomes. A list of ART publications is available at http://www.cdc.gov/art/publications/. Other data may not be released in order to protect the ART patient's confidentiality. However, CDC has established a way that researchers outside of CDC can securely access limited, de-identified NASS data to conduct analyses. CDC's Research Data Center, housed within the National Center for Health Statistics, allows researchers to analyze restricted data in a secure environment after their proposed research has been reviewed and approved by CDC.

14. How does CDC ensure the confidentiality of the ART data it collects?

CDC has an Assurance of Confidentiality for the ART database. An Assurance of Confidentiality is a formal confidentiality protection authorized under Section 308(d) of the Public Health Service Act (42 U.S.C. 242[m]). An assurance is used for projects conducted by CDC staff or contractors involving the collection or maintenance of sensitive, identifiable, or potentially identifiable information. The assurance allows CDC programs to assure that individuals and institutions involved in research or nonresearch projects protect the confidentiality of the data collected. Under Public Health Service Act Section 308(d), no identifiable information may be used for any purpose other than that for which it was supplied unless such institution or individual has consented to that disclosure. CDC's current Assurance of Confidentiality for this project is ongoing.

15. Why doesn't the report contain specific medical information about ART?

This report describes a woman's average chances of success per ART cycle. Although the report provides some information about factors such as age and infertility diagnosis, consumers face many unique medical situations. This population-based registry of ART procedures cannot capture detailed information about specific medical conditions associated with infertility. Consumers should consult with their physician to understand their specific medical situation and their chances of success using ART.

16. Why are statistics in the Fertility Clinic Tables published by CDC different from statistics reported by SART's IVF Success Rate Reports?

During 1996–2013, the percentage of ART clinics with a SART membership reporting data to CDC ranged from approximately 82% to 95%. Annual summary statistics of ART treatments performed in each of these clinics are available online at http://www.sart.org. For the same table items that are presented in both the CDC's Fertility Clinic Tables and SART's IVF Success Rate Reports, discrepancies in tabulated statistics between the SART and CDC tables may be due to (1) the inclusion in the CDC Fertility Clinic Reports of ART treatments performed at non-SART member clinics; (2) differences in the data submission deadlines between SART and CDC, which may result in ART clinics being excluded from CDC's annual Fertility Clinic Reports; and (3) differences in data processing procedures and statistical methods used to generate statistics.

17. Does CDC have any information on the women who donate eggs?

CDC only collects information on the age of egg donors, but does not present it in the individual clinic tables for this report. In 2013, the average age of egg donors was approximately 26 years. Success rates for cycles using donor eggs or using embryos derived from donor eggs is related to the age of the woman who produced the eggs. Thus, the percentage of transfers that resulted in live births for cycles using fresh embryos from donor eggs remained consistently high—above 55% among most patients of different ages.

18. Are there any medical guidelines for ART performed in the United States?

ASRM and SART issue guidelines dealing with specific ART practice issues, such as the number of embryos to be transferred in an ART procedure. Further information can be obtained from ASRM or SART (both at telephone 205-978-5000 or at websites http://www.asrm.org and http://www.sart.org).

19. Where can I get additional information on US fertility clinics?

For further information on specific clinics, contact the clinic directly (see Appendix C: ART Clinics on pages 533–574 for current contact information). In addition, SART can provide general information on its member clinics (telephone 205-978-5000, extension 109).

20. What's new in the 2013 report?

CDC is constantly striving to present the most accurate and relevant ART clinic success rates to help potential patients make decisions. Changes to the clinic table and National Summary table format have been made to provide a more comprehensive and user-friendly presentation of clinic and national success rates data. Highlights of modifications designed to enhance clarity, readability, and improve the presentation of data include the following:

2013 ART Success Rates Section

- Modification of the total number of ART cycles performed to include the total number of cycles using frozen eggs for each clinic (indicated in parentheses).
- Removal of outcomes per pregnancy for fresh embryo cycles from nondonor eggs.
- Addition of a measure, percentage of cycles and transfers resulting in term, normal weight, and singleton live births.
- Replacement of the percentage of cycles per transfer resulting in triplet or more live births with the percentage of cycles per transfer resulting in twin live births, and the addition of this measure for donor egg cycles.
- Addition of the number of egg/embryo banking cycles by age of the woman.